

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 01 March 2001 (01.03.01)	Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/US00/16628	Applicant's or agent's file reference 175980
International filing date (day/month/year) 16 June 2000 (16.06.00)	Priority date (day/month/year) 18 June 1999 (18.06.99)
Applicant CHO-CHUNG, Yoon, S.	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

18 January 2001 (18.01.01)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer F. Baechler
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference 175980	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/16628	International filing date (day/month/year) 16/06/2000	Priority date (day/month/year) 18/06/1999	
International Patent Classification (IPC) or national classification and IPC G01N33/574			
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA...			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 18/01/2001	Date of completion of this report 20.09.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Bigot-Maucher, C Telephone No. +49 89 2399 7415



INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

International application No. PCT/US00/16628

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-37 as originally filed

Claims, No.:

1-20 as originally filed

Drawings, sheets:

1/17-17/17 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/16628

the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.

claims Nos. 1-18 with respect to novelty and inventive step; 18-20 with respect to industrial applicability.

because:

the said international application, or the said claims Nos. 18-20 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-18 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the standard.

the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/16628

No: Claims 19-20
Inventive step (IS) Yes: Claims
No: Claims 19-20
Industrial applicability (IA) Yes: Claims 1-17
No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Item III:

1. Claims 18-20 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
2. No opinion with regard to novelty and inventive step will be given for claims 1-18, since it cannot unambiguously be derived from the description what the term "ECPKA" refers to (Article 6 PCT). It cannot be derived from the prior art either, since said term is not known in the art.

On the one hand it appears from the passage on p 9, I 5-7 of the present description that ECKPA and PKA are the same substances. Furthermore, on p 9, last par, the advice is given that cell lysis should be kept to a minimum so that the determination of PKA accurately reflects the amount of ECPKA and not intracellular PKA. Moreover, ECPKA is immunologically related to intracellular PKA (p 33, I 9-10). ECPKA is a type I PKA (p 33, I 26).

On the other hand, ECPKA and PKA I do not seem to be the same substance, since an antibody seems to exist which can distinguish between ECPKA, intracellular PKA and ecto-PKA (p 20, last par).

A further possibility is that ECPKA is the C subunit of PKA (p 37, I 8-9).

If ECKPA is a novel substance, then the invention is furthermore not considered to be disclosed sufficiently clear and complete to be carried out by a person skilled in the art (Article 5 PCT) for the following reasons. No deposited example of ECKPA or of an antibody recognizing ECKPA is provided. The information on p 9, last par, that an antibody to a subunit of ECKPA can be used for the determination of ECPKA, is insufficient, since the skilled person has no possibility to get such an antibody from a substance he doesn't know.

Item V:

Reference is made to the following documents:

D1: **ANTISENSE & NUCLEIC ACID DRUG DEVELOPMENT,**
vol. 6, no. 3, 1996, pages 237-244

D2: **CHEMICAL ABSTRACTS,**
vol. 125, no. 13, 23 September 1996 (1996-09-23) Columbus, Ohio, US;
abstract no. 159637

1. Articles 33(2) and (3) PCT

1.1. The subject-matter of independent claim 19 relates to a method of treating cancer in a patient comprising administering to said patient a recombinant vector that is targeted to cancer cells and expresses an effective amount of a mutant of the R α subunit of PKA in said cancer cells.

The subject-matter of **independent claim 19 does not appear to be novel** (Article 33(2) PCT) in the light of the prior art:

D1 already discloses a method for inhibiting tumor growth *in vivo* comprising injecting an R α antisense construct (i.e. a vector) (p 241, 1 col, 2nd par ff).

D2 describes the inhibition of tumor growth after injection of an R α antisense oligonucleotide into mice (p 9, example 2).

1.2. **The same applies to dependent claim 20**, since the additional feature of said dependent claim is purely conventional and does not lead to an unexpected effect.

2. Industrial Applicability

For the assessment of the present claims 18-20 on the question whether they are industrially applicable, no unified criteria exist in the PCT contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16628

example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Item VII:

The vague and imprecise statement "spirit and scope of the invention" (p 37, last lines) implies that the subject-matter for which protection is sought may be different to that defined in the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them (see the Guidelines, C-III, 4.3a). This statement has not been amended to remove inconsistency.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 175980	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/ 16628	International filing date (day/month/year) 16/06/2000	(Earliest) Priority Date (day/month/year) 18/06/1999
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA...		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of **5** sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. Certain claims were found unsearchable (See Box I).

3. Unity of Invention is lacking (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

EXTRACELLULAR CAMP-DEPENDENT PROTEIN KINASE IN DIAGNOSIS, PROGNOSIS AND TREATMENT OF CANCER

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

5a _____

None of the figures.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-17

Methods for diagnosing and prognosticating cancer and determining the hormone dependency of breast cancer in a patient by assaying for the presence of extracellular cAMP-dependent protein kinase.

2. Claims: 18-20

Methods for treatment of cancer in a patient by inhibiting the expression of protein kinases.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/16628

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 G01N33/574 G01N33/573 A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Y. S. CHO-CHUNG: "Protein kinase A-directed antisense restrains cancer growth: Sequence-specific inhibition of gene expression." ANTISENSE & NUCLEIC ACID DRUG DEVELOPMENT., vol. 6, no. 3, 1996, pages 237-244, XP002151893 MARY ANN LIEBERT, INC., NEW YORK., US ISSN: 1087-2906 the whole document ----	1, 10, 11
Y	---- -/--	18-20

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

2 November 2000

Date of mailing of the international search report

20/11/2000

Name and mailing address of the ISA

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 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Griffith, G

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/16628

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CHEMICAL ABSTRACTS, vol. 125, no. 13, 23 September 1996 (1996-09-23) Columbus, Ohio, US; abstract no. 159637, J. M. S. BARTLETT ET AL.: "Analysis of cAMP RI alpha mRNA expression in breast cancer: Evaluation of quantitative polymerase chain reaction for routine use." page 270; column 1; XP002151894 abstract & BR. J. CANCER, vol. 73, no. 12, 1996, pages 1538-1544, ---	1-17
A	WO 97 03090 A (UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER) 30 January 1997 (1997-01-30) page 54, line 1 - line 8; claims 1-12	1-17
Y	page 51, line 29 -page 52, line 2 ---	18-20
Y	EP 0 785 252 A (Y. S. CHO-CHUNG) 23 July 1997 (1997-07-23) the whole document ---	18-20
Y	G. TORTORA ET AL.: "An antisense oligodeoxynucleotide targeted against the type II beta regulatory subunit mRNA of protein kinase inhibits cAMP-induced differentiation in HL-60 leukemia cells without affecting phorbol ester effects." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA., vol. 87, January 1990 (1990-01), pages 705-708, XP002031228 NATIONAL ACADEMY OF SCIENCE. WASHINGTON., US ISSN: 0027-8424 the whole document ---	18-20
Y	Y. S. CHO-CHUN ET AL.: "A RI alpha subunit antisense oligodeoxynucleotide of cAMP-dependent protein kinase blocks proliferation in human and rodent cancer cell lines by-passing exogenous cAMP effect." PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, vol. 31, March 1990 (1990-03), page 29 XP002031229 *abstract 171* ---	18-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/16628

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9703090	A 30-01-1997	US 5723300 A		03-03-1998
		AU 6761696 A		10-02-1997
EP 785252	A 23-07-1997	US 5271941 A		21-12-1993
		EP 0972831 A		19-01-2000
		AT 156517 T		15-08-1997
		AT 194383 T		15-07-2000
		CA 2054325 A		03-05-1992
		DE 69127175 D		11-09-1997
		DE 69127175 T		12-03-1998
		DE 69132299 D		10-08-2000
		DK 490077 T		26-01-1998
		EP 0490077 A		17-06-1992
		ES 2104644 T		16-10-1997
		GR 3024673 T		31-12-1997
		JP 8310958 A		26-11-1996
		JP 2719060 B		25-02-1998
		JP 6211889 A		02-08-1994
		KR 171210 B		01-02-1999
		US 5627158 A		06-05-1997
		US 5691317 A		25-11-1997
		ZA 9203666 A		22-11-1993



(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

Published:

— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

In. National Application No
PCT/US 00/16628

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N33/574 G01N33/573 A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data

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Y	— —/—	18-20

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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

2 November 2000

20/11/2000

Name and mailing address of the ISA

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Authorized officer

Griffith, G

INTERNATIONAL SEARCH REPORT

In. National Application No

PCT/US 00/16628

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	<p>WO 97 03090 A (UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER) 30 January 1997 (1997-01-30) page 54, line 1 - line 8; claims 1-12</p>	1-17
Y	<p>page 51, line 29 -page 52, line 2</p>	18-20
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Y	<p>Y. S. CHO-CHUN ET AL.: "A RI alpha subunit antisense oligodeoxynucleotide of cAMP-dependent protein kinase blocks proliferation in human and rodent cancer cell lines by-passing exogenous cAMP effect." PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, vol. 31, March 1990 (1990-03), page 29 XP002031229 *abstract 171*</p>	18-20

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-17

Methods for diagnosing and prognosticating cancer and determining the hormone dependency of breast cancer in a patient by assaying for the presence of extracellular cAMP-dependent protein kinase.

2. Claims: 18-20

Methods for treatment of cancer in a patient by inhibiting the expression of protein kinases.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9703090	A 30-01-1997	US 5723300 A	US 6761696 A	03-03-1998 10-02-1997
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		AT 156517 T	AT 194383 T	15-08-1997 15-07-2000
		CA 2054325 A	CA 69127175 D	03-05-1992 11-09-1997
		DE 69127175 T	DE 69132299 D	12-03-1998 10-08-2000
		DK 490077 T	DK 0490077 A	26-01-1998 17-06-1992
		ES 2104644 T	ES 3024673 T	16-10-1997 31-12-1997
		GR 8310958 A	JP 2719060 B	26-11-1996 25-02-1998
		JP 6211889 A	JP 171210 B	02-08-1994 01-02-1999
		US 5627158 A	US 5691317 A	06-05-1997 25-11-1997
		ZA 9203666 A		22-11-1993